

## Form 81 - Pelvic Exam

Data File: f81\_ep\_fu\_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

**Participant ID** 

Variable # 1

Usage Notes: none

Sas Name: ID

Categories: Study: Administration

Sas Label: Participant ID Continuous Type:

F81 Days since randomization

Days between randomization and the date the form was initiated

Variable # 2

Usage Notes: none

Usage Notes: none

Sas Name: F81DAYS

Sas Label: F81 Days since randomization

Categories: Study: Administration

Categories: Study: Administration

Continuous Type:

F81 Visit type

Variable # 3

Sas Name: F81VTYP

Sas Label: Visit type

Categorical Type:

**Values** 

Screening Visit Semi-annual Visit 3 **Annual Visit** 

Non Routine Visit

F81 Visit number

Number of the visit for which this form was collected.

Sas Name: F81VNUM

Variable # 4

Sas Label: Visit number

Continuous Type:

Usage Notes: none

Categories: Study: Administration

F81 Days from randomization to pelvic exam date

Variable # 5

Usage Notes: none

Sas Name: PELVICDY

Sas Label: Days from rand to pelvic exam

Clinical Tests: Pelvic Exam Categories:

Reproductive

Type: Continuous

> 11/10/2005 Page 1 of 9



#### Form 81 - Pelvic Exam

File Date: 04/12/2005 Data File: f81\_ep\_fu\_pub **Structure:** Multiple rows per participant Population: E+P participants

Categories:

F81 Pelvic exam performed by

Variable # 6

Sas Name: PELVICBY

Sas Label: Pelvic exam performed by

Categorical Type:

**Values** 

CC staff Other

Usage Notes: none

Clinical Tests: Pelvic Exam Categories:

Reproductive

F81 Doctor found anything wrong

Were there any abnormal findings found during the pelvic exam?

Variable # 7

Sas Name: PLVABNRM

Sas Label: Doctor found anything wrong

Type: Categorical

**Values** 

No

Usage Notes: Sub-question of F81 V6 Q6 "Pelvic exam performed by".

Not collected on all versions of Form 81.

Clinical Tests: Pelvic Exam

Reproductive

Yes

## F81 Loss of adipose tissue

External genitalia (vulva): loss of adipose tissue

Variable # 8

Sas Name: ADIPOSE

Sas Label: Loss of adipose tissue

Type: Categorical

**Values** 

No Yes, probably benign Yes, possibly malignant Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

## F81 Thinning of hair

External genitalia (vulva): thinning of hair

Sas Name: PLVHAIR

Variable # 9

Sas Label: Thinning of hair

Type: Categorical Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

Values

Yes, probably benign Yes, possibly malignant

> 11/10/2005 Page 2 of 9



# Form 81 - Pelvic Exam

Data File: f81\_ep\_fu\_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

F81 Genitalia - Abnormal discoloration

External genitalia (vulva): abnormal discoloration

Variable # 10

Sas Name: DISCVLVA

Sas Label: Genitalia - Abnormal discoloration

Type: Categorical

**Values** 

0 No
1 Yes, probably benign
2 Yes, possibly malignant

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Genitalia - Ulceration

External genitalia (vulva): ulceration

Variable # 11

Sas Name: ULCERVLV

Sas Label: Genitalia - Ulceration

Type: Categorical

**Values** 

0 No
1 Yes, probably benign
2 Yes, possibly malignant

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Genitalia - Growth

External genitalia (vulva): growth

Variable # 12

Sas Name: GROWVLVA
Sas Label: Genitalia - Growth

Type: Categorical

Values

NoYes, probably benignYes, possibly malignant

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Atrophy

Variable # 13

Sas Name: ATROPHY

Sas Label: Atrophy

Type: Categorical

**Values** 

0 No
1 Yes, probably benign
2 Yes, possibly malignant

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

Page 3 of 9 11/10/2005



#### Form 81 - Pelvic Exam

Data File: f81\_ep\_fu\_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

F81 Vagina - Smooth

Variable # 14

Sas Name: PLVSMTH

Sas Label: Smooth

Type: Categorical

**Values** 

0 No

1 Yes, probably benign

Yes, possibly malignant

Usage Notes: Not collected on all versions of Form 81

Not required if "Pelvic exam performed by" is "Other"...

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Pale

Variable # 15

Sas Name: PLVPALE

Sas Label: Pale

Type: Categorical

**Values** 

0 No

1 Yes, probably benign

Yes, possibly malignant

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Friable with contact

Variable # 16

Sas Name: FRIABVAG

Sas Label: Vagina - Friable with contact

Type: Categorical

Values

0 No

1 Yes, probably benign

Yes, possibly malignant

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Blood present

Variable # 17

Sas Name: BLOODVAG
Sas Label: Blood present

Type: Categorical

Values

No
Yes, probably benign
Yes, possibly malignant

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

Page 4 of 9 11/10/2005



#### Form 81 - Pelvic Exam

Data File: f81\_ep\_fu\_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

F81 Vagina - Abnormal discoloration

Variable # 18

Sas Name: DISCVAG

Sas Label: Vagina - Abnormal discoloration

Type: Categorical

**Values** 

0 No

1 Yes, probably benign

Yes, possibly malignant

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Ulceration

Variable # 19

Sas Name: ULCERVAG

Sas Label: Vagina - Ulceration

Type: Categorical

**Values** 

0 No

1 Yes, probably benign

2 Yes, possibly malignant

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Growth

Variable # 20

Sas Name: GROWVAG

Sas Label: Vagina - Growth

Type: Categorical

Values

0 No

1 Yes, probably benign

Yes, possibly malignant

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Cystocele

Variable # 21

Sas Name: CYSTOCEL

Sas Label: Cystocele

Type: Categorical

Values

0 None
1 Grade 1 (in vagina)
2 Grade 2 (to introitus)
3 Grade 3 (outside vagina)

Usage Notes: Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

Page 5 of 9 11/10/2005



#### Form 81 - Pelvic Exam

File Date: 04/12/2005 Structure: Multiple rows per participant Data File: f81\_ep\_fu\_pub Population: E+P participants

F81 Vagina - Rectocele

Variable # 22

Usage Notes: Not required if "Pelvic exam performed by" is "Other".

Sas Name: RECTOCEL

Sas Label: Rectocele

Categorical Type:

Clinical Tests: Pelvic Exam Categories:

Reproductive

**Values** 

None Grade 1 (in vagina) Grade 2 (to introitus) Grade 3 (outside vagina)

F81 Cervix (absent/present)

Variable # 23

Sas Name: PLVCERVX

Sas Label: Cervix

Type: Categorical

**Values** 

Absent Present

Usage Notes: Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories: Reproductive

F81 Cervix - Flush with vaginal vault

Variable # 24

Sas Name: CRVFLUSH

Sas Label: Flush with vaginal vault

Type: Categorical

Values

Yes, probably benign Yes, possibly malignant Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

F81 Cervix - Friable with contact

Variable # 25

Sas Name: FRIABCRV

Sas Label: Cervix - Friable with contact

Categorical Type:

Values

No Yes, probably benign Yes, possibly malignant Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

11/10/2005 Page 6 of 9



### Form 81 - Pelvic Exam

Data File: f81\_ep\_fu\_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

## F81 Cervix - Surface lesion/growth

Cervix: surface lesion/growth (other than ectopy, Nabothian cyst)

Variable # 26
Sas Name: LESION

Sas Label: Surface lesion/growth

Type: Categorical

Values

0 No
1 Yes, probably benign
2 Yes, possibly malignant

Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Cervix - Polyp

Variable # 27

Sas Name: POLYP

Sas Label: Polyp

Type: Categorical

**Values** 

0 No
1 Yes, probably benign
2 Yes, possibly malignant

Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

#### F81 Uterus

Uterus (absent/present/unable to palpate)

Variable # 28

Sas Name: PLVUTER
Sas Label: Uterus

Type: Categorical

Values

0 Absent
1 Present
9 Unable to palpate

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Uterus - Prolapse

Variable # 29

Sas Name: PROLAPSE
Sas Label: Prolapse

Type: Categorical

71

Values

None
Grade 1 (in vagina)
Grade 2 (to introitus)
Grade 3 (outside vagina)

Usage Notes: Sub-question of F81 V6 Q10 "Uterus".

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

Page 7 of 9 11/10/2005



#### Form 81 - Pelvic Exam

File Date: 04/12/2005 Structure: Multiple rows per participant Data File: f81\_ep\_fu\_pub Population: E+P participants

F81 Uterus - size (weeks)

Variable # 30

Sas Name: UTERSIZE

Sas Label: Uterine size (weeks)

Continuous Type:

Usage Notes: Sub-question of F81 V6 Q10 "Uterus".

Not required if "Pelvic exam performed by" is "Other".

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

F81 Uterus - Enlarged since last exam

Variable # 31

Sas Name: UTERENLR

Sas Label: Enlarged since last exam

Type: Categorical

Values

No Yes Usage Notes: Sub-question of F81 V6 Q10 "Uterus".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Adnexae

Adnexae (normal/mass present/unable to palpate)

Variable # 32

Sas Name: ADNEXAE Sas Label: Adnexae

Categorical Type:

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

**Values** 

Normal Mass present Unable to palpate/absent

F81 Mass present

Adnexae: location of mass

Variable # 33 Sas Name: MASSLOC

Sas Label: Mass present

Type: Categorical Usage Notes: Sub-question of F81 V6 Q11 "Adnexae".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam Categories:

Reproductive

**Values** 

1	Right				
2	Left				
3	Both				

11/10/2005 Page 8 of 9



#### Form 81 - Pelvic Exam

File Date: 04/12/2005 Structure: Multiple rows per participant Data File: f81\_ep\_fu\_pub Population: E+P participants

F81 Pap smear obtained

Variable # 34

Sas Name: PAPSMEAR

Sas Label: Pap smear obtained

Categorical Type:

**Values** 

No, not done No, send for outside report Yes, vaginal smear Yes, Pap smear

Usage Notes: Not collected on all versions of Form 81.

Clinical Tests: Pelvic Exam Categories:

Reproductive

F81 Referral made for follow-up

Was a referral made for follow-up care (pelvic exam)?

Variable # 35

Sas Name: PLVREFER

Sas Label: Referral made for follow-up

Type:

Categorical

**Values** 

No Yes Usage Notes: none

Categories:

Clinical Tests: Pelvic Exam

Reproductive

F81 Days from randomization to PE referral

Variable # 36

Sas Name: PLVREFDY

Sas Label: Days from rand to PE referral

Type: Continuous Usage Notes: Sub-question of F81 V6 Q13 "Referral made for follow-up".

Clinical Tests: Pelvic Exam Categories:

Reproductive

F81 Pelvic follow-up results

Variable # 37

Sas Name: PLVFURES

Sas Label: Pelvic follow-up results

Type: Categorical

Values

Normal Benign changes Possibly malignant Usage Notes: Sub-question of F81 V6 Q13 "Referral made for follow-up".

Not collected on all versions of Form 81.

Clinical Tests: Pelvic Exam Categories:

Reproductive

11/10/2005 Page 9 of 9